Reviewer's report

Title: Comparison of Published Orthopaedic Trauma Trials Following Registration in ClinicalTrials.gov

Version: 2 Date: 19 October 2011

Reviewer: Olav Reikerås

Reviewer's report:

In this study the authors performed a review of trials registered in ClinicalTrials.gov (CTG) relating to orthopaedic trauma evaluating publication rates and consistency of reporting. The hypothesis was that the incidence of registered trials not published would be high despite mandatory reporting of clinical trials, and there would be methodological differences between publication and registration methodology. They found that only 16 of 37 (43.2%) trials registered in CTG resulted in publication as of March 2011 and that final results of completed trials were not reported in the registry, and many publications were inconsistent in sample size and reporting of outcomes with the original report in CTG.

The study is of general interest and thereby deserves publication.

However, there are some questions that the authors should underline and/or discuss.

The Introduction should specify more the original intention to establish a CTG register, and they should explain the meaning of NCT.

Also they should explain why/how the NCT ID in the final publication can allow the reader to evaluate the strength of the trial by comparing it to the original plans. This is only stated.

Furthermore, much of the information in Results should be presented in Methods.

In Discussion the authors focuses on strengths of the study, but all studies have limitations, and the authors should also focus on these.

In the Conclusion the authors state that "When trials are registered, a great number of them do not cite the registration number in the publication, making it impossible for the reader to evaluate the study conclusions in relation to the original plans for the trial."

Why is this so, and is this a conclusion?

Furthermore, the authors conclude that "We suggest all journals should make registration of clinical trials mandatory for publication."

Why is this so, and is this a conclusion?